

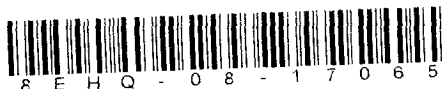


The Chemical Company

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January 21, 2008



Via Federal Express

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United States Environmental Protection Agency - East
Attn: TSCA Section 8(e)
Room 6428
1201 Constitution Avenue, NW
Washington, DC 20004

Subject: Notice in Accordance with TSCA Section 8(e): Interim results of a Prenatal Developmental Toxicity Study in Himalayan Rabbits with bis(2-ethylhexyl)-1,4-benzenedicarboxylate (CAS No. 6422-86-2)

Dear Sir/Madam:

BASF Corporation is submitting results of a prenatal developmental toxicity study in Himalayan Rabbits [CrI:CHBB(HM)] with bis(2-ethylhexyl)-1,4-benzenedicarboxylate (CAS No. 6422-86-2), conducted by BASF Aktiengesellschaft, Ludwigshafen, Germany. The test substance is a plasticizer.

The study was carried out with reference to the requirements of the following guidelines:

- Corrigendum to EC Commission Directive 2004/73/EC, Part B (29 Apr 2004): Methods for the determination of toxicity: Prenatal Developmental Toxicity Study; Official Journal of the European Union, No. L 216, pp. 227-235 (2004)
- EPA Health Effects Test Guidelines, OPPTS 870.3700: Prenatal Developmental Toxicity Study (August 1998)
- OECD Guideline for Testing of Chemicals; Proposal for updating Guideline 414: Prenatal Developmental Toxicity Study (22 Jan 2001)

The test substance was administered by gavage to 25 artificially inseminated female rabbits/group at doses of 0, 750 and 1000 mg/kg body weight/day. The duration of treatment was designed to be on day 6 through day 28 post insemination.

The following is a summary of the most relevant results:

The high dose (1000 mg/kg bw/d) of the test material produced distinct signs of maternal toxicity, such as drastically reduced food consumption (majority of animals completely ceased eating), reduced body weight and body weight gain as well as clinical observations like reduced or no defecation.

BASF Corporation
100 Campus Drive
Florham Park, NJ 07932
Tel: (800) 526-1072
www.basf.com/usa



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Based on these findings, the high dose was reduced from 1000 mg/kg bw/d to 500 mg/kg bw/d at day 20 p.i. Because the clinical situation of the high dosed animals did not improve, and abortions were observed in a number of animals, the administration was stopped. Even so, no improvement was observed, one doe had to be sacrificed moribund, and another 3 does aborted. Blood in bedding and abortion were noted in a total of 6 out of 25 does. Therefore, the high-dose group was completely sacrificed for humane reasons. The animals were necropsied and the uterine contents of all animals were inspected macroscopically. The most prominent necropsy findings were stomachs, filled with very dry and hard feed in 19/25 does, and stomach ulcerations in 6/25 does. 22/25 animals were pregnant.

Distinctly reduced food consumption, reduced body weight and body weight gain as well as clinical observations such as reduced defecation, no defecation and blood in bedding were also noted for the mid-dose group. Therefore, the dose was reduced from 750 mg/kg bw/d to 250 mg/kg bw/d at day 20 p.i. Thereafter, no improvement was observed with regard to the clinical situation in most of the animals of this dose group. Therefore, animals that were in a moribund status were sacrificed for humane reasons. Eight animals survived until scheduled sacrifice. All animals were necropsied and the uterine contents were inspected macroscopically. The most prominent necropsy findings were stomachs filled with very dry and hard feed in 9/25 does and stomach ulcerations in 7/25 does. 24/25 animals were pregnant. No treatment-related findings were noted in the offspring of the 8 survivors in terms of fetal weight, external and soft tissue examination. Skeletal examination is ongoing.

BASF Corporation understands that reporting of the results from this study under TSCA 8(e) is in accordance with EPA's policy.

If you have any questions, please call Janet Cerra at (973) 245-6693.

Sincerely,

Janet Cerra

Janet Cerra
Product Regulatory Center of Excellence

/jc

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BASF Corporation
100 Campus Drive
Florham Park, NJ 07932
Tel: (800) 526-1072
www.basf.com/usa

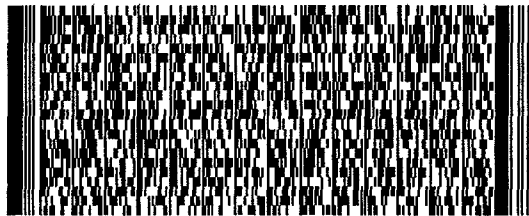
From: Origin ID: LKKA (973)245-6693
Janet Cerra
BASF
100 Campus Drive

Florham Park, NJ 07932



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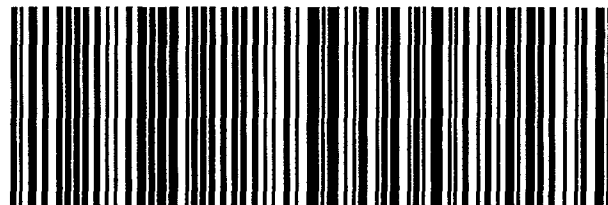
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